COLORADO
Department of Health Care Policy & Financing

MINUTES OF THE QUARTERLY OPEN MEETING OF THE COLORADO MEDICAID DUR BOARD

University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences at the Anschutz Medical Campus, 12850 E. Montview Boulevard, Aurora

May 12, 2015 7:00 PM to 9:00 PM

1. Call to Order

The meeting was officially called to order at 7:20 PM by R Page.

2. Roll Call

The Board Coordinator called the roll. There were not sufficient members for a quorum with 4 members participating and 4 members excused.

A. **Members Present:** James 'Rick' Kant, RPh , Edra Weiss, MD, David Block (Industry Representative), Sheila Botts, PharmD, Kerstin Froyd, MD

B. **Medicaid Pharmacy Staff:** Nila Mahyari, PharmD, Robert Page, PharmD, Medicaid Pharmacy Department: Robert Lodge, PharmD

C. **Members Excused:** LeWayne Garrison, RPh, James Regan, MD, Pam Reiter, PharmD, Karen Weber, DO

3. Approval of Minutes

After an introduction of DUR Board members, R Page asked if there were any changes or needed discussion of the minutes from the last meeting. The minutes were recommended to be approved.

4. Department Updates

R Lodge announced that despite the absence of a quorum to vote at the current meeting, it has been agreed upon by the DUR Board to continue discussion of criteria in order to provide recommendations for the Department.

N Mahyari provided updates regarding newly updated HCPF Tobacco Cessation Policy. Changes include the removal of the first prior authorization required for short-acting nicotine replacement therapy (NRT) and allowance for coverage of combination short-acting and long-acting NRT

R Lodge provided updates related to policies surrounding growth hormones and antivirals used to treat HepC. He outlined the changes in policy to the preferred product coverage under the category of growth hormones and the efforts of the Department in ensuring a safe and convenient transition for Medicaid beneficiaries from Nordiptropin ® to Genotropin ®, the new preferred product. R Lodge also described the implementation of the interim criteria for HepC agents and the Department's efforts to make this a smooth process ensuring that those members that are denied coverage have the right to appeal this decision via the administrative court.

5. Rules

R Page asked the Board if any conflicts of interest existed for the drugs and classes reviewed. None were reported by the Board.

R Page announced the rules for Oral Presentations:

- Presentations shall be restricted to products being reviewed for prior authorization criteria.
- Presentations shall be limited to a maximum of five minutes per drug product. Only one presentation per product will be permitted for a manufacturer. Persons must sign up no later than 24 hours in advance with the DUR Account Manager in order to speak at the DUR Board Meeting.
- Persons giving oral presentations must disclose all relationships to pharmaceutical manufacturers.
- Persons will be called in the order in which they signed in for each set of prior authorization criteria.
- Presentations must be limited to verbal comments. No visual aids, other than designated handouts are permitted.

6. Open Comments

1. Testosterone Products

Preferred: Angrogel 1.62%®(Testosterone topical)
Androderm® (Testosterone topical)
Depo Testosterone® (Testosterone injection)
Generic Depo® Testosterone (Testosterone injection)

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class*		
	January 2015	February 2015	March 2015
Testosterone Cypionate	47%	47%	47%
Androgel	31%	31%	32%

Testosterone injection (12mg, 25 mg, 50 mg)	8%	8%	9%
Axiron	3%	3%	3%
Depo Testosterone	3%	3%	<1%
Testim	1%	1%	1%
Fortesta Gel	<1%	<1%	<1%

Prior Authorization Criteria:

Hypogonadotropic or Primary Hypogonadism

Preferred androgenic drugs will be approved for members meeting the Following:

1. Male patient ≥ 18 years of age AND
2. Has a documented diagnosis of hypogonadotropic or primary hypogonadism (Patients with other diagnoses will require a manual review by a state pharmacist) AND
3. Has two documented low serum testosterone levels below the lower limit of normal range for testing laboratory prior to initiation of therapy AND
4. Does not have a diagnosis of breast or prostate cancer AND
5. Does not have a palpable prostate nodule or prostate-specific antigen (PSA) > 4ng/mL AND
6. Has normal liver function tests prior to initiation of therapy

Gender Transition

Preferred androgenic drugs will be approved for members meeting the Following:

1. Biologically born female patient ≥ 18 years of age* AND
2. Is undergoing female to male transition AND
3. Has a negative pregnancy test prior to initiation AND
4. Has normal liver function tests prior to initiation of therapy

*For members < 18 years of age, a manual review will be required.

Nonpreferred androgenic drugs will be approved for patients meeting the above criteria with documented failure with an 8 week trial of a preferred androgenic drug (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction)

Grandfathering: Members may be grandfathered on preferred agents without requirement of updated low serum testosterone laboratory testing that meet the following criteria:

- Male patient ≥ 18 years of age AND
- Has at least one past documented low serum testosterone levels below the lower limit of normal range for testing laboratory prior to initiation of therapy AND
- Has documented diagnosis of hypogonadotropic or primary hypogonadism AND
- Does not have a diagnosis of breast or prostate cancer AND
- Does not have a palpable prostate nodule or prostate-specific antigen (PSA) > 4ng/mL

Discussion

There was discussion surrounding the need for re-testing and acquiring of two low testosterone levels for members new to Medicaid that have been stabilized on therapy. K Froyd states that it is not appropriate to test but it is reasonable to obtain old labs to confirm low results.

It was recommended to approve the above criteria with the highlighted amendments.

2. Fibromyalgia Agents

Preferred: Lyrica® (Pregabalin)
Duloxetine

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class*		
	January 2015	February 2015	March 2015
Lyrica® (Pregabalin)	53%	53%	53%
Duloxetine	37%	37%	38%
Savella® (Milnacipran)	9%	10%	9%
Cymbalta®	<1%	<1%	<1%

*Based on patients> 18 years of age without an ICD-9 for 345.xx

Prior Authorization Criteria:
Non-preferred agents will be approved for fibromyalgia
if member has failed an adequate trial (8 weeks) of both Lyrica and duloxetine OR
the member has contraindication to Lyrica and duloxetine

For members with no epilepsy diagnosis in the last two years
(as confirmed by SMART PA), PA will be required for LYRICA
prescriptions requiring more than 3 capsules per day or for
prescriptions requiring doses greater than 600mg per day.

GENERIC DULOXETINE will be approved if the member has
diagnosis for fibromyalgia

Discussion

It was recommended to approve the above criteria.

3. Angiotensin Receptor Blockers/ARB Combinations

Preferred: Irbesartan
Benicar ® (olmesartan)
Diovan® (valsartan)
Losartan
Benicar -HCT® (olmesartan/HCTZ)
Diovan-HCT ® (valsartan/HCTZ)
Losartan-HCTZ

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2015	February 2015	March 2015
Losartan	78%	78%	78%
Diovan® (valsartan)	10%	9%	10%
Irbesartan	4%	4%	4%
Benicar® (olmesartan)	6%	6%	6%
Valsartan	2%	2%	2%
Atacand® (candesartan)	<1%	<1%	<1%
Telmisartan	<1%	<1%	<1%
Micardis® (telmisartan)	<1%	<1%	<1%

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2015	February 2015	March 20154
Losartan-HCTZ	68%	67%	68%
Diovan HCT® (valsartan/HCTZ)	20%	20%	20%
Benicar-HCT® (olmesartan/HCTZ)	12%	13%	13%
Edarbyclor® (azilsartan medoxomil /chlorthalidone)	<1%	<1%	<1%
Telmisartan/HCTZ	<1%	<1%	<1%
Avalide-HCT® (irbesartan/HCTZ)	<1%	<1%	<1%
Exforge® (valsartan/amlodipine)	<1%	<1%	<1%
Tribenzor® (olmesartan/amlodipine)	<1%	<1%	<1%
Valsartan HCTZ	<1%	<1%	<1%

HCTZ: hydrochlorothiazide

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2015	February 2015	March 2015
Tekturna® (Aliskiren)	100%	100%	100%

HCTZ: hydrochlorothiazide

Prior Authorization Criteria:

Non-preferred ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products will be approved for members who have failed treatment with three preferred products in the last 12 months (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.).

Renin-inhibitors and combinations
will not approved in patients with diabetes. Receiving an ACE-inhibitor, ACE-inhibitor combination, ARB, or ARB-combination in combination with a renin inhibitor is contraindicated.

Discussion

It was recommended to approve the above criteria.

4. Long Acting Opiates

Preferred: Methadone
Morphine ER
Fentanyl Patches
Tramadol ER

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2015	February 2015	March 2015
Morphine Sulfate ER	48%	47%	46%
Fentanyl Patch	20%	20%	20%
Oxycontin® (oxycodone ER)	14%	14%	14%
Methadone (generic)	14%	14%	13%
Nucynta ER® (tapentadol)	2%	2%	2%
Oxymorphone ER	1%	1%	1%
Opana ER® (oxymorphone)	<1%	<1%	<1%
Hydromorphone ER	<1%	<1%	<1%
Tramadol ER	<1%	<1%	<1%
Butrans® (buprenorphine)	<1%	<1%	<1%
Avinza® (morphine)	<1%	<1%	<1%
Xartemis XR® (oxycodone/APAP)	<1%	<1%	<1%
Zohydro ER ® (hydrocodone)	<1%	<1%	<1%
Duragesic Patch® (fentanyl)	<1%	<1%	<1%
MS Contin® (morphine)	<1%	<1%	<1%

APAP: Acetaminophen

Prior Authorization Criteria:
Non-preferred, long-acting oral opioids will be approved for members who have failed treatment with two preferred agents in the last six months. (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.)

Fentanyl patches (Duragesic) will require a PA for doses of more than 1 patch/2 days.

BUTRANS will be approved for members who have failed treatment with one preferred agent in the last six months. (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.)

ZOHYDRO ER® will be approved for members who have failed treatment with two preferred products, AND at least one other long acting opiate in the past year.

OXYCONTIN®, OPANA ER®, NUCYNTA ER®, and ZOHYDRO ER® will only be approved for twice daily dosing.

No more than one long acting opioid will be approved at one time.

Medicaid is not mandating that a patient switch from a non-preferred drug to methadone. Methadone requires special training due to its complex pharmacokinetic profile. However, if a patient has tried methadone in the past, then it may be considered one trial of one preferred drug.

Use of opioid analgesics during pregnancy has been associated with neonatal abstinence syndrome. Providers MUST counsel women of childbearing age regarding the risks of becoming pregnant while receiving opioids, including the risk of neonatal abstinence syndrome. Providers should offer access to contraceptive services when necessary.

Discussion

The following individuals provided comment to the Board on the above topic:
Dr. Mark Juhn (Pfizer) – Naloxone and high risk of abuse with opioids
It was recommended to approve the above criteria with the highlighted amendments.

5. Topical Immunomodulators

Preferred: Elidel® (pimecrolimus)

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2015	February 2015	March 2015
Elidel ® (pimecrolimus)	95%	95%	96%
Tacrolimus	5%	4%	4%
Protopic® (tacrolimus)	0%	<1%	0%

Prior Authorization Criteria:
Prior authorization is required for children < 2 years of age.
Prior authorization will be required for members warranting ≥ 6 weeks of therapy with either ELIDEL or PROTOPIC.

ELIDEL® will only be approved for a member who had an adequate trial (e.g, one month or longer) of a topical steroid and failed treatment. (Failure is defined as a lack of efficacy, allergy, intolerable side effects, or significant drug-drug interactions.)

PROTOPIC® will only be approved for a member who had an adequate trial (e.g, one month or longer) of a topical steroid and Elidel and failed treatment. (Failure is defined as a lack of efficacy, allergy, intolerable side effects, or significant drug-drug interactions.)

Discussion

It was recommended to approve the above criteria.

6. Skeletal Muscle Relaxants

Preferred: Baclofen
Cyclobenzaprine
Tizanidine

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2015	February 2015	March 2015
Cyclobenzaprine	64%	64%	65%
Baclofen	18%	17%	18%
Tizanidine	17%	17%	17%
Methocarbamol	<1%	<1%	<1%
Metaxolone	<1%	<1%	<1%
Carisoprodol	<1%	<1%	<1%
Dantrolene	<1%	<1%	<1%
Orphenadrine ER	<1%	<1%	<1%
Chlorzoxazone	<1%	<1%	<1%
Amrix ER®(cyclobenzaprine)	<1%	<1%	<1%
Skelaxin ® (metaxolone)	<1%	<1%	<1%
Dantrium® (dantrolene)	<1%	0%	0%

Prior Authorization Criteria:

All agents in this class will require a prior authorization for members over 65 years of age. Approval will only be given if the member has had at least a 7 day trial with an opiate or has a diagnosis of spasticity. The maximum allowable approval will be for a 7 day supply.

Non-preferred skeletal muscle relaxants will be approved for members Who have documented lack of efficacy with two preferred agents in the last 6 months.(Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interactions.)

Authorization for any CARISOPRODOL product will be given for a maximum 3week one time authorization for members with acute, painful musculoskeletal conditions who have failed treatment with two preferred products.

Tapering:
Due to potential withdrawal symptoms, tapering is recommended when discontinuing high doses of CARISOPRODOl. A one month approval will be granted for members tapering off of CARISOPRODOl.

*A PA will only be granted for any carisoprodol product for short-term use or

tapering

Discussion

It was recommended to approve the above criteria.

7. Newer Generation Antihistamines/Antihistamine Combinations

Peferred: Loratadine
Cetirizine

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2015	February 2015	March 2015
Cetririzine	70%	70%	70%
Loratadine	25%	26%	26%
Fexofendadine	3%	3%	3%
Levocetirizine	<1%	1%	<1%
Desloratadine	<1%	<1%	<1%
Xyzal® (levocetirizine)	<%	<1%	<1%
Clarinex® (desloratadine)	<1%	<1%	0%

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2015	February 2015	March 2015
Loratadine-D	100%	100%	100%

PSE: pseudoephedrine

Prior Authorization Criteria:
Non-preferred antihistamines and antihistamine/decongestant combinations will be approved for members who have failed treatment with two preferred products in the last 6 months and including nasal steroids (for children age 4 and older). (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.)

Discussion

It was recommended to approve the above criteria with the highlighted amendments.

8. Inhaled Anticholinergics/Anticholinergic Combinations

Preferred: Albuterol/Ipratropium
Ipratropium
Atrovent HFA®(ipratropium)
Combivent Respimat ® (albuterol/Ipratropium)
Spiriva Handihaler® (tiotropium)

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2015	February 2015	March 2015

Spiriva Handihaler® (tiotropium)	92%	91%	91%
Ipratropium	6%	7%	7%
Tuorza Pressair (aclidinium)	2%	2%	2%

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2015	February 2015	March 2015
Albuterol/Ipratropium	98%	98%	98%
Anoro Ellipta® (umeclidinium/vilanterol)	2%	2%	2%

Prior Authorization Criteria:
ATROVENT® and DUONEB ® will require a brand-name prior Authorization stating medical necessity.

Non-preferred anticholinergic agents will be approved for members with a diagnosis of COPD including chronic bronchitis and/or emphysema who have failed treatment with Spiriva Handihaler® (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction), or who have a contraindication to Spiriva Handihaler.

Non-preferred combination anticholinergic agents will be approved for members with a diagnosis of COPD including chronic bronchitis and/or emphysema AND has failed treatment with Combivent Respimat® (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction), OR who have a contraindication to Combivent Respimat®.

Discussion:
The following individuals provided comment to the Board on the above topic:
Bill O'Neil (BI) – Spiriva Respimat
It was recommended to approve the above criteria.

9. Short Acting Inhaled Beta-2 Agonists

Preferred: Albuterol solution
Proair HFA® (albuterol)

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2015	February 2015	March 2015
Proair HFA®(albuterol)	79%	77%	79%
Albuterol solution	19%	22%	19%
Ventolin HFA®(albuterol)	<1%	<1%	<1%
Xopenex HFA® (levalbuterol)	<1%	<1%	<1%
Proventil HFA® (albuterol)	<1%	<1%	<1%

Prior Authorization Criteria:
Non-preferred, short acting beta2 agonists will be approved for members who have failed treatment with one preferred agent. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction).

Quantity limits: 2 inhalers / 30 days (will go into effect September 2015)

10. Long Acting Inhaled Beta-2 Agonists

Preferred: None

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2015	February 2015	March 2015
Serevent Diskus®(salmeterol)	38%	37%	51%
Perforomist ® solution (formoterol)	27%	27%	21%
Foradil®(formoterol)	18%	12%	16%
Brovana® solution (arformoterol)	14%	22%	9%
Arcapta® (indacaterol)	3%	2%	3%
Striverdi® (indacaterol)	0%	0%	1%

Prior Authorization Criteria:
Long acting beta-2 agonists will be approved for members with moderate to severe asthma who are currently using an inhaled corticosteroid and require add-on therapy, or for members with moderate to very severe COPD.

Possible RETRO: look into how to separate asthma treatment from COPD while not allowing for single LABA use in asthma (BBW)

Discussion
It was recommended to approve the above criteria with the highlighted amendments and recommendations inserted for retrospective analysis ideas.

11. Inhaled Corticosteroids

Preferred: Asmanex® (mometasone)
Budesonide
Flovent HFA® (fluticasone)
Flovent diskus®(fluticasone)
QVAR®(beclomethasone)

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2015	February 2015	March 2015
Flovent HFA® (fluticasone) Flovent Diskus® (fluticasone)	35%	36%	35%
QVAR® (beclomethasone)	36%	33%	35%
Budesonide	18%	20%	18%
Asmanex® (mometasone)	4%	4%	4%
Pulmicort Flexhaler® (budesonide)	3%	3%	3%
Alvesco® (ciclesonide)	3%	2%	3%
Aerospan® (flunisolide)	<1%	<1%	<1%

Prior Authorization Criteria:
Non-preferred inhaled corticosteroids will be approved
in members with asthma who have failed
an adequate trial of two preferred agents
An adequate trial is defined as at least 6 weeks.
(Failure is defined as: lack of efficacy, allergy,
intolerable side effects, or significant drug-drug interactions.)

PULMICORT FLEXHALER® will only be approved for female members
with asthma who have a new diagnosis of pregnancy.

BUDESONIDE NEBULIZER will only be approved for a maximal
dose of 2mg/day.

Discussion
It was recommended to approve the above criteria.

12. Inhaled Corticosteroid Combinations

Preferred: Advair Diskus ® (fluticasone/salmeterol)
Advair HFA® (fluticasone/salmeterol)
Dulera® (mometasone/formoterol)

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2015	February 2015	March 2015
Advair Diskus® (fluticasone/salmeterol) Advair HFA® (fluticasone/salmeterol)	75%	76%	75%
Dulera® (mometasone/formoterol)	20%	19%	20%

Symbicort® (budesonide/formoterol)	4%	4%	4%
Breo Ellipta®(fluticasone/vilanterol)	<1%	<1%	<1%

Prior Authorization Criteria:
Non-preferred inhaled corticosteroid combinations will be approved for members meeting both of the following criteria:

- Member has a qualifying diagnosis of asthma or COPD; and
- Members with a diagnoses of asthma has failed two preferred agents due to lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction.

Members with a diagnosis of COPD will only have to fail one preferred agent due to lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction.

Discussion
It was recommended to approve the above criteria.

13. Xartemis XR (oxycodone/acetaminophen)

In 11/2014, we reviewed criteria for Xartemis XR® and could not reach consensus on appropriate criteria as per recommended by the DUR Board Members. At that time, the Department attempted to write criteria which would allow the use of this agent for those with a high risk of drug abuse due to the mixed pharmacokinetics of Xartemis XR® dosage form. Albeit, the criteria as written was controversial due to the lack of evidence for the use of this agent in this population and the criteria was tabled for a future meeting. The Department has recommended placement of this drug in the long-acting segment of the PDL after consultation with a pain specialist, because of high risk of dose stacking, and increased number of units on-hand if asked to fail other short-acting agents.

14. Movantik (naloxegol):

Prior Authorization Criteria

MOVANTIK® will be approved for members who meet the following criteria:

- Member has diagnosis of constipation associated with chronic opioid use associated with non-cancer pain AND
- Opioid use must exceed 4 weeks of treatment AND
- Member must not be taking oral CYP3A4 inhibitors AND
- Member does not have diagnosis of GI obstruction AND
- Member has failed the following additive bowel regimens (failure is defined as lack of efficacy after 7 days of treatment with all three agents):
  - ✓ Stimulant e.g. Senna, Docusate Sodium
  - ✓ Osmotic Agents e.g. Miralax® or Lactulose
  - ✓ Nonphosphate Enema

Discussion:

The following individuals provided comment to the Board on the above topic:
Devechio Edwards (AstraZeneca) – Movantik

K Froyd recommended to specify using a nonphosphate enema. It was recommended to approve the above criteria with the highlighted amendments.

15. Relistor (methylnaltrexone bromide)

Prior Authorization Criteria

RELISTOR® will be approved for members who meet the following criteria:

- Member has diagnosis of constipation associated with chronic opioid use associated with late-stage, advanced illness pain AND
- Member opioid use must exceed 4 weeks of treatment AND
- Member does not have diagnosis of GI obstruction AND
- If the member can take oral medications, the member has failed the following additive bowel regimens (failure is defined as lack of efficacy after 7 days of treatment with):
  - ✓ Stimulant e.g. Senna, Docusate Sodium
  - ✓ Osmotic Agents e.g. Miralax® or Lactulose
  - ✓ Nonphosphate Enema
  - ✓ OR
- If the member cannot take oral medications, then the member has failed a 7-day trial of with a nonphosphate enema.

Discussion:
K Froyd recommended to specify using a nonphosphate enema. It was recommended to approve the above criteria with the highlighted amendments.

16. Tybost (Cobicistat)

Prior Authorization Criteria

TYBOST® will be approved for members who meet the following criteria:

- Member has diagnosis of HIV-1 AND
- Member is currently being treated with atazanavir or darunavir only AND
- Member is not taking a cobicistat-containing drugs, or ritonavir-containing drugs AND
- Member has failed treatment with ritonavir (failure defined as intolerable side effect, allergy, or
  lack of efficacy).

Disuccsion:
It was recommended to approve the above criteria

17. Horizant (gabapentin enacarbil

Prior Authorization Criteria

HORIZANT® will be approved for members who have a diagnosis of
Restless Leg Syndrome and who meet the following criteria:

- Member has failed a one month trial of Mirapex® (pramipexole) and Requip® (ropinorole) AND
- Member has had a positive therapeutic response to generic gabapentin but incomplete due to duration of action.

Max quantity: 30 tablets/30 days

HORIZANT ®will be approved for members who have a diagnosis of

Post Herpetic Neuralgia and who meet the following criteria:

- Member has failed a one month trial of tricyclic antidepressant, pregabalin and gabapentin

Max quantity: 60 tablets / 30 days

Disuccsion:
It was recommended to approve the above criteria.

18. Methotrexate Auto-injectors

Prior Authorization Criteria:
METHOTREXATE AUTOINJECTOR authorization will be approved for members who meet the following criteria:

- Member has diagnosis for rheumatoid arthritis AND
- Member cannot take methotrexate by mouth due to intolerable gastrointestinal side effects AND
    - Member cannot take an injection due to limited functional ability.

Disuccsion:
It was recommended to approve the above criteria with the highlighted amendments.

19. Bunavail (buprenorphine/naloxone)

Prior Authorization Criteria:
BUNAVAIL® buccal film will be approved for members who meet the following criteria:

- Approval will be granted if prescriber meets the qualification criteria under Drug Addiction Treatment Act (DATA) of 2000 and has been issued a unique DEA identification number by the DEA, indicating that he or she is qualified under the DATA to prescriber Subutex® or Suboxone® AND
- The member has a diagnosis of opioid dependence AND
- The member is 16 years of age or older AND
- No claims data show concomitant use of opiates in the preceding 30 days AND
- The member must have tried and failed, intolerant to, or has contraindication to generic buprenorphine/naloxone SL tablets.

Disuccsion:
It was recommended to approve the above criteria.

20. Evizo (naloxone injection)-Tabled

EVZIO will be tabled as of right now and reviewed case by case.

21. Daliresp (roflumilast)

Prior Authorization Criteria:
DALIRESP® tablets will be approved for members that meet the following criteria:

- Member has a diagnosis for severe COPD with history of COPD exacerbations (2 or more per year) and chronic bronchitis AND
- Member must be greater than 18 years of age AND
- Member must have failed a trial of two of the following: long-acting beta2 agonist, preferred anticholinergic/anticholinergic combination, or preferred inhaled anticholinergic/anticholinergic combinations due to lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction AND
- Member must not have moderate to severe liver disease (Child Pugh B or C).

Note: this medication is not a bronchodilator and cannot be used for acute bronchospasms

Disuccsion:
It was recommended to approve the above criteria with the highlighted amendments.

22. Cholbam (cholic Acid)

Prior Authorization Criteria:
CHOLBAM capsules will be approved for members who meet the following criteria:
Bile acid synthesis disorders:

- Member must be greater than 3 weeks old in age AND
- Member has a diagnosis for bile acid synthesis disorder due to single enzyme defect (Single Enzyme-Defect Disorders: Defective sterol nucleus synthesis, 3β-hydroxy-Δ-c27-steroid oxidoreductase deficiency, AKR1D1 deficiency, CYP7A1 deficiency, Defective side-chain synthesis, CYP27A1 deficiency (cerebrotendinous xanthomatosis), 2-methylacyl-CoA racemase deficiency (AMACR), 25-hydroxylation pathway (Smith–Lemli-Opitz).

Peroxisomal disorder including Zellweger spectrum disorders:

- Member must be greater than 3 weeks old in age AND
- Member has diagnosis of peroxisomal disorders (PDs) including Zellweger spectrum disorders AND
- Member has manifestations of liver disease, steatorrhea or complications from decreased fat soluble vitamin absorption.

Discussion:
It was recommended to approve the above criteria.

7. The meeting was adjourned at 8:51 p.m.

The meeting adjourned at 8:51 PM.

I, R Page, PharmD, as Acting Chair of the Colorado Medicaid DUR Board, hereby attest that these minutes substantially reflect the substance of the discussion during the open session.

By: _____

R Page, PharmD, Acting Committee Chair

Date: _____

Reasonable accommodations will be provided upon request for persons with disabilities. Please notify the DUR Coordinator Robert Lodge at 303- 866-xxxx or or email him at Robert.lodge@state.co.us at least one week prior to the meeting.